QUALITY MANAGEMENT PLAN

QMP

for

WED

Western Ecology Division (WED)
National Health and Environmental Effects Research Laboratory (NHEERL)
United States Environmental Protection Agency (EPA)
Corvallis, OR 97333

Quality Management Plan

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FOREWORD

The Environmental Protection Agency deals with some of the most important yet divisive issues confronting the U.S. Government . As a highly visible regulatory agency it is absolutely essential that EPA's environmental regulations and policies are based on concepts and data that are accurate, reliable, and representative of the true situation . To help assure that research quality meets agency needs, the National Health and Environmental Effects Research Laboratory, Western Ecology Division (WED) operates a comprehensive Quality Assurance and Quality Control Program . The Quality Assurance Manager is responsible to assure that the quality of all research conducted by or for this division is commensurate with its intended use.

This program has three key components: The first is *planning* . It is the responsibility of the research managers (Branch Chiefs, Program Leader and Project Leaders) to develop and implement comprehensive plans for all research conducted or funded within their area of responsibility . All Research Plans are subjected to scientific peer review, and Quality Assurance Plans are reviewed for specific measures of quality by the WED Quality Assurance Staff.

The second is *implementation* . The functional responsibility for implementing the approved plans, assuring the quality of data, and reporting the results is assigned to a Project Leader.

The third is *independent review* provided by the Quality Assurance Manager (QAM) . The QAM's role is very different from that of the Branch Chiefs . The QAM is responsible for certifying that all research is conducted according to the procedures described in an approved QA plan . Because independence, both real and perceived, is fundamental to Quality Assurance, the QAM reports to the Associate Division Director for Science.

The division's QA program is a prime element in assuring that the quality of WED research is commensurate with Agency needs . Please join me in providing your complete support for the Division's quality assurance program.

3/19/01

Jennifer Orme Zavaleta
Associate Director for Science WED

Date

NOTE:
This document can be viewed on-line or downloaded from: http://www.epa.gov/wed/pages/QA/internetQMP.wpd or http://www.epa.gov/wed/pages/QA/internetPDFQMP.pdf The blue highlighted areas are hyperlinks to the document indicated . For those reading this from paper, a list of all web links is included at the end.

ACRONYMS used in this QMP

EPA	**E**nvironmental **P**rotection **A**gency
DQA	**D**irector of Quality **A**ssurance
DQO	**D**ata **Q**uality **O**bjectives
LOE	**L**evel **O**f **E**ffort contract
MSR	**M**anagement **S**ystem **R**eview . In the context of QA, this is a review of the lab QMP and it's implementation by the DQA and assigned staff from NHEERL.
NHEERL	**N**ational **H**ealth and **E**nvironmental **E**ffects **R**esearch **L**aboratory
ORD	**O**ffice of **R**esearch and **D**evelopment
PE	**P**erformance **E**valuation
PI	**P**rincipal **I**nvestigator
PL	**P**roject **L**eader
PO	**P**roject **O**fficers, the title given by financial management policy to the manager of an extramural project.
QA	**Q**uality **A**ssurance
QAA	**Q**uality **A**ssurance **A**udit
QAM	**Q**uality **A**ssurance **M**anager . This refers to the person designated by the division director to lead the quality assurance staff at WED
QAPP	**Q**uality **A**ssurance **P**roject **P**lan
QC	**Q**uality **C**ontrol
QMP	**Q**uality **M**anagement **P**lan
SOP	**S**tandard **O**perating **P**rocedure
WAM	**W**ork **A**ssignment **M**anager, EPA project manager for work performed by contract.
WED	**W**estern **E**cology **D**ivision

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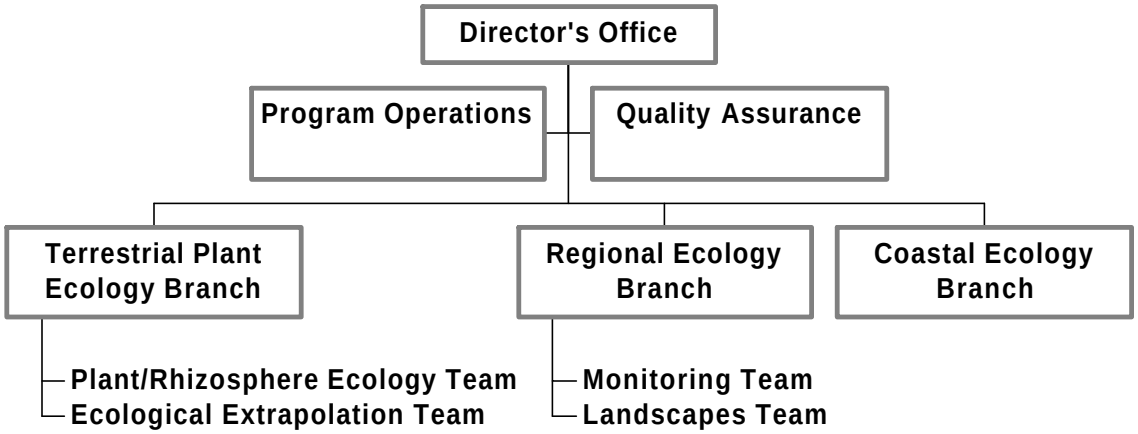
INTRODUCTION

The U.S. Environmental Protection Agency (EPA) requires that all data collected or used by or for the Agency comply with a series of steps to assure the quality of the research . The basic policy is contained in EPA ORDER 5360.1 A2 May 5, 2000 *POLICY AND PROGRAM REQUIREMENTS FOR THE MANDATORY AGENCY-WIDE QUALITY SYSTEM* which follows the standards described in the ANSI/ASQC E4-1994: *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* . The EPA Quality Manual for Environmental Programs provides program requirements for implementing the order.

This document provides guidance to all persons associated with or funded by WED. It defines Quality Assurance Program goals, methods for attaining those goals, and explains basic and general responsibilities.

MANAGEMENT and ORGANIZATION

Western Ecology Division, NHEERL



Research is authorized, planned, and executed by EPA research managers . The names designating various management positions are generally associated with the function they perform.

Project leader is the federal employee given authority and responsibility to conduct all administrative and technical aspects of a project. Funding jargon defines the following special types of project leaders:

- **Work Assignment Manager** (**WAM**) is a project leader who manages research related services done by a contract.
- **Project Officer** indicates a manager of a project conducted by a Cooperative Agreement or Interagency Agreement.

Responsibilities for Quality Assurance

Division Director has ultimate responsibility for all research conducted, funded, or managed within the division . He/she must approve the division QMP.

Branch Chiefs are responsible for the quality of research conducted, funded, or managed within their branches **.** They must approve QAPPs, and manuscripts . They may delegate approval authority for SOPs to the program or project leaders.

Project Leaders (PL) manage and monitor all the work, including QA, within the project . They must approve QAPPs, SOPs, and manuscripts that pertain to their projects. Any of the following items can be delegated to PIs or others for implementation, but the PL remains responsible for their establishment and execution.

Key QA/QC responsibilities of Project Leaders:

- Establish data quality objectives, specifications, and acceptance criteria for the project.
- Ensure that an approved QAPP exists prior to start up of any research activity.
- Ensure that the procedures specified in the QAPP are being followed.
- Ensure that QA reports specified in the QAPP are received in a timely manner and copies are forwarded to the QA office for review.
- Evaluate the QA reports and assure that results are commensurate with the expectations specified in the QAPP.
- Prepare a QA Review Form which accompanies each funding action (for extramural projects).
- Interact with the PI regarding QA/QC.
- Identify the need for, and initiate, appropriate corrective actions.
- Verify that adequate supportive QA/QC documentation is available for each research output . Ensure that all outputs comply with the technical output clearance process.

Institution Project Manager is the person at an extramural institution who is assigned to manage the project that is being done for or in cooperation with WED.

Principal Investigator (**PI**) is the person charged with conducting a research project or a part of a project (task) . Depending on the project there may be one or several principal investigators and they may be either EPA employees or cooperators in extramural institutions . The PI is the person who generally conceives experiments, analyzes data, and writes research reports, and thus generally appears as the primary author . A PI may or may not be one of the following: the Project Leader, Institution Project Manager, Program Leader, Branch Chief, etc . Duties of the PI are negotiated with the PL and are detailed in the QAPP.

Researchers and/or **Technicians** (intramural or extramural) are responsible for conducting technical tasks and for ensuring the quality of the results generated . Key QA/QC responsibilities are designated by the PI and may include:

- Participate in preparing the QAPP.
- Document QC output(s).
- Follow established procedures, such as SOPs, and document any deviations.
- Perform and document preventive maintenance as necessary.
- Maintain up-to-date laboratory notebooks and/or other appropriate record-keeping systems.
- Report to the PI all QA problems encountered and corrective actions taken.

Quality Assurance Office is part of the Office of the Division Director . This administrative arrangement avoids potential conflicts with operational programs and provides **independent review** of QA matters . The Quality Assurance staff consists of the Quality Assurance Manager (QAM), and other experienced scientists assigned on a rotational basis (part-time) typically for one or two years . Their duties are to assist in all aspects of the QA program.

The **Quality Assurance Manager** (QAM) is responsible for ensuring that all WED QA activities are in compliance with agency QA policy and guidance . He/she reports to the Associate Division Director for Science . Key responsibilities of the QAM are:

- Certify that quality assurance project plans (QAPPs) and standard operating procedures (SOPs) meet QA agency standards.

- Review funding actions for extramural projects and certify compliance with QA/QC policy.
- Review all scientific outputs for compliance with division and agency policies dealing with research quality.
- Prepare the QMP.
- Review the QMP annually, and propose revisions as appropriate.
- Prepare an annual status report describing activities that demonstrate compliance with policies for all research conducted or funded by the division.
- Track the QA/QC status of WED projects.
- Conduct audits of QA procedures in WED projects.

Delegation of Authority: In the absence of the QAM, a senior member of the QA staff or the Associate Division Director for Science may sign in the QAM's stead.

QUALITY SYSTEM and DESCRIPTION

Peer review and the QA program are the key tools used at WED to assess research quality . Elements of the WED Quality Assurance Program are:

Quality Management Plan (QMP)

The QMP sets forth the basis for the division's quality assurance program . It identifies roles and responsibilities of managers and scientists regarding research quality.

The first page carries the signatures of those who have approved and committed to follow the procedures that have been outlined . It provides the basis for assessing the effectiveness of the WED Quality Assurance Program . It provides an outline for periodic management system reviews (MSRs) conducted by NHEERL . These reviews are to assist WED in complying with current EPA policy and procedures and assure the NHEERL director that WED is in compliance with those policies . The QMP will be reviewed annually by the QAM, and if needed, minor changes made by amendment which will be approved by the Division Director and Branch Chiefs at WED . The QMP must be re-approved by the NHEERL Director of Quality Assurance (DQA) every five years.

Graded Approach:

Since different research projects are associated with different levels of public awareness and have different immediate applications, a graded approach to project oversight is needed . Each project will be assigned a category according to the criteria in the NHEERL QMP:

Category I: Research which directly and/or immediately supports specific Agency rule-making, enforcement, regulatory, or policy decisions . This category may also include research of significant national interest, such as tasks that might be monitored by the Administrator . It may also include research conducted under a Cooperative Research and Development Agreement, more commonly known by the acronym CRADA, or other technology transfer project for which the data and/or the research conduct by which the data were obtained may be critical to the award of a patent or other important commercial or legal decision.

Category II: Research of high programmatic relevance which, in conjunction with other ongoing or planned studies, is expected to provide complementary support of Agency rule-making, regulatory, or policy decisions.

Category III: Demonstration or proof of concept projects; method validation studies.

Category IV: Basic, exploratory, conceptual research to study basic phenomena or issues . Includes the characterization of health or ecological mechanisms and/or endpoints in order to improve the understanding of the interaction of environmental compounds, conditions, or processes with human and other life forms; and also includes development of assays or methods for detecting or estimating the influence of a particular environmental agent on a specified health or ecological endpoint.

Assignment of the category is the responsibility of the Project leader with concurrence by the brach chief and division director.

Quality Assurance Project Plan (QAPP)

All research must be performed in compliance with an **approved QAPP**. This specifically includes: (see EPA order 5360.1 A2 section 5.b.)

(1) the characterization of environmental or ecological systems and the health of human populations;
(2) the direct measurement of environmental conditions or releases, including sample collection, analysis, evaluation, and reporting of environmental data;
(3) the use of environmental data collected for other purposes or from other sources (also termed "secondary data"), including literature, industry surveys, compilations from computerized data bases and information systems, results from computerized or mathematical models of environmental processes and conditions;

Any document which is supplemental (principally SOPs) to the QAPP and which defines or prescribes procedures that contribute to the quality of data, is considered an integral part of the QAPP and therefore also requires approval .

Since the implementation of the quality system is a management responsibility, the appropriate research manager must approve QA planning documents . QAPPs must be approved by branch chiefs and SOPs may be approved by any manager designated by the branch chief . The QAM certifies that the plans presented in the QAPP or SOP meet WED standards .

Many good and useful ideas regarding research are not envisioned prior to experimentation and are therefore not included in QAPPs or SOPs . When such creative ideas are conceived, authority to implement them is given by the Project Leader and if the new activity alters the QA procedures, a written note will be forwarded to the QAM . This note will constitute an amendment to the applicable QAPP or SOP and will be reviewed and then added to the appropriate document.

Exceptions from having a complete QAPP may be authorized by the branch chief with compliance of the QAM for preliminary work . Exceptions are authorized for a designated time (normally less than 6 months) and are typically authorized to evaluate a procedure or concept prior to writing a QAPP . Request for exemption should be submitted in a memo from the project leader, thru the branch chief, to the QAM . It should contain an explanation of the intended work, reasons for wanting an exemption, requested period and include appropriate signatures.

Projects involving measurement of environmental parameters must be organized according to Agency policy . The requirements are contained in: EPA Requirements for QA Project Plans (QA/R-5) and guidance for writing in: Guidance on Quality Assurance Project Plans (G-5) . Abbreviated guidance and some examples is contained in Appendix 3 of this QMP for writing QAPPs at WED. Format is less important than the utility of a QAPP. If the suggested format compromises the usefulness, each writer should feel constrained by the latter as long as all elements needed to specify quality are included.

Projects not involving measurement of environmental parameters should follow the same general format with modifications specific to the type of activity . These projects may be the basis for important decisions and, although they do not generate new data, attention to the origin and quality of data used in environmental evaluation is vital . The QAPP should direct the attention of scientists towards explaining the limits or constraints of assumptions and the inherent error associated with data transformations . Some models allow error propagation while others may suggest sensitivity analysis as a method of evaluating error . There should be a discussion of whether the results are expected to be quantitative, comparative, or heuristic . QAPP guidelines for model development are found in "Quality assurance guidelines for modeling development and application projects: a Policy Statement" (Appendix 4).

Data Quality Objectives (**DQO**s) establish the data user's requirements for precision, accuracy, completeness, representativeness, and comparability . Defining the DQOs is an important initial step of the QA planning process and they become part of the QAPP .

When data are being used to select between two alternative conditions (e.g., compliance or non-compliance with a standard), the Agency's recommended systematic planning tool is the Data Quality Objectives (DQO) Process . This system consists of the following steps and is detailed in: Guidance for the Data Quality objectives Process E PA QA/G-4

- State the problem
- Identify the decision
- Identify the inputs to the decision
- Define the boundaries of the study
- Develop a decision rule
- Specify tolerable limits on decision errors
- Optimize the design for obtaining data

Most environmental research conducted at WED is associated with identifying ecological concepts and patterns and describing ecosystem relationships . Although the results of this research are critical to the development of standards, regulations, and remediation policies, they are rarely used to resolve a problem or define a level of action as may be required at a hazardous waste or superfund site . The steps outlines in the DQO process (G-4) are therefore not specifically required, however the concepts discussed and the steps suggested to identify and clarify goals and needed data quality are useful and should be followed to the extent applicable . The PI should decide the data quality needed to adequately test the proposed hypothesis . Consideration of available measurement technology and costs often dictate the possibilities of data quality.

Standard Operating Procedures (**SOP**s) may be prepared at any time for any routine activity . Branch management approval (may be delegated by the branch chief to the project leader) and QAM certification is required for all procedures which define activities that contribute to the quality of data . When approved, the SOP can be referenced by any QAPP and thus functionally becomes a part of that plan.

A useful format for organizing a SOP should follow most of the sections in the format for the QAPP (Appendix 3) . A SOP should be written in sufficient detail to be used as a method for the persons performing the procedure.

QA review of Manuscripts: The QA office has the responsibility for reviewing all manuscripts to verify compliance with agency QA standards as described in the Publication Review and Clearance Procedures (WED Policy #2260.1) . Most manuscripts result from research described in an approved QAPP . Relationship to the appropriate QAPP should be specified on the ORD Clearance form (ORD 362 Rev 2/97). If the manuscript is unrelated to a QAPP or is disassociated from data (i.e., position paper, editorial, etc.), an explanation is needed on the review form . The review form should be completed and accompany the manuscript when first submitted to the QA staff for review.

PERSONNEL QUALIFICATIONS and TRAINING

Research managers are responsible for assuring that each employee has the necessary qualifications and job proficiency for assigned work . This typically includes formal education in a scientific discipline and on-the-job experience.

Prior to beginning technical work at WED, each scientist and technician is required to attend a New Employee Orientation which includes training in laboratory safety and an introduction to WED quality assurance policy.

Besides the training required to administer extramural projects (including certification for managing contracts), Project Leaders should be familiar with appropriate QA requirements and practices.

The QAM at WED is required to be an experienced scientist who is trained in subjects relating to environmental science . The staff are also scientists . All are expected to be familiar with all WED and Agency QA policies to facilitate the research effort at WED . Training will be vigorously pursued as time and funds are available.

PROCUREMENT of ITEMS and SERVICES

Cooperative Agreements (COOP), Interagency Agreements (IAG), Contracts . Since **all** research must be performed in compliance with an approved QAPP, prospective applicants for WED assistance should be sent a copy of the WED QMP so they understand the extent of planning expected . A special condition of any funding vehicle for research, analysis, or sample collection should include a statement stipulating that no research can begin until a QAPP has been approved.

At the discretion of the EPA Project Leader, the QAPP may be required as part of the proposal or be required only from successful applicants . It is recommended that, as a minimum, all proposals should include a QA capability statement or institutional QMP . In general, the QA capability statement is a qualitative statement of the offeror's QA/QC capabilities, whereas the QAPP provides a quantitative discussion.

Some extramural activities depend so heavily on the performance of QA/QC procedures that the QAPP should be required as part of the proposal and should constitute a significant portion of the evaluation . These projects are typically those that are primarily for the collection or analysis of environmental samples . At the discretion of the Project Leader, Requests for Proposals (RFPs) for projects involving environmental measurements may have part of the evaluation criteria dedicated to QA . Agency guidelines recommend that at least five (5) percent, and not more than thirty (30) percent, of the total possible score be based on QA criteria . The Project Leader should identify the percent of the evaluation points applicable to QA.

Each **Contract, COOP** or **IAG** funding action is reviewed by the QA staff to determine compliance to Division and Agency policy . The project leader must complete and submit, with the request for funding, the FUNDING CLEARANCE Quality Assurance Review form . For continuation or incremental funding of ongoing projects, the QA staff evaluates evidence of compliance with an approved QAPP . The evidence includes: QA reports, audits, notes from the EPA Project Leader and extramural project managers, manuscripts, and performance evaluations.

Work Assignments: Research conducted by **LOE** contracts is directed by work assignments (WA) . Although the contracting organization must have a QMP which describes their corporate commitment and policy regarding quality (EPA ORDER 5360.1 A2 May 5, 2000), authorization to conduct research is based on the approved QAPPs . A WA may assign work on one or many projects . The Work Assignment Quality Assurance Review form is used to identify the projects involved and includes the WAM's signature indicating that all QA/QC requirements are being met on all projects involved . The QAM reviews the status of project approval, required reports, manuscripts, and correction of any findings from audits and if complete certifies that the projects are in compliance with QA requirements.

DOCUMENTS and RECORDS

QA Files Official (signature approved) copies of QAPPs and SOPs, along with audit reports, progress reports, and communications regarding QA are to be kept by the Project Leader.

WED QA office has adopted the paper-less office concept . Records are organized using the database FOX PRO® . The system is maintained on a division server and write-access allowed only by passwords issued to the QAM . The QA office keeps a copy of QAPPs, SOPs, audit reports, manuscript reviews, and approval of funding packages . The QA office also keeps a record of receipt, assignment, decisions, and return of each of the approximately 350 documents received yearly . Read-

only access to the tracking system is available to anyone on the local area network . Access to the tracking system will allow a person to determine the disposition of his/her document.

Newly entered data are backed-up by copying to tape at the end of each working day and the entire compliment of QA files is copied to tape weekly . This procedure ensures that records are permanent and that if any computer problem occurs, only work from the preceding day may be lost.

Copies of final QA documents (QAPP, SOP) will be requested for the QA office in a computer format . Documents which include information not available on computer format (i.e.,some graphics) may be forwarded on paper . The location of all paper files will be recorded in the computer project identification file . QA office files (paper and electronic) are maintained for five years following approval and publication of all manuscripts and/or the project leader declares the project complete.

WED quality management plans (QMP) will be kept as PDF files in the QA database for twenty years following the approval of a more recent version. The current version will be available from the WED web page, and back versions will be available upon request to the QAM.

Annual QA Report The QAM will submit to the WED Associate Director for Science a fiscal year report of QA activities, by 31 October, including recommendations for possible changes to the WED QMP.

PLANNING

Two planning documents are required for all projects before the collection of data or research activity can begin. These are:

A peer reviewed **Research Plan** documents the research activities to be performed and the resources needed to implement the plan . The form of this Research Plan can vary substantially depending on the type of research being conducted.

A **Quality Assurance Project Plan (QAPP)** documents the processes which assure data quality. (see Appendix 3 for format).

Research plans and QAPPs may be developed intramural or by extramural cooperators or contractors . Scientific progress is regularly monitored by division management and peer review . Division and ORD's policy requires biennial peer review of each research program.

ASSESSMENT and RESPONSE

There are two principal means (Quality Assurance Audit and the Performance Evaluation) to determine compliance with an WED approved QA program. These procedures are used to verify that measurement systems are operating properly, to determine that data quality is adequately documented, and to evaluate management of the QA program.

Quality Assurance Audit (**QAA**, QA Audit, or simply Audit) consists of a thorough on-site evaluation of a research activity . Audits are used to evaluate the existence and adequacy of all equipment, facilities, supplies, personnel, and procedures that are either used directly for, or in support of, the collection and interpretation of data . In addition, audits are used to evaluate the documentation associated with data quality indicators . Audits will be planned by the QAM with assistance from the QA staff and EPA Project Leader. The QAM has the lead responsibility for carrying out audits . Audits are designed to complement the peer review process by assuring that any QA issues that may affect the scientific credibility of the data are brought to the investigator's attention.

Audits are conducted by a member of the WED QA staff or a duly appointed, federally employed person . Anyone conducting an audit must be independent from the performing or authorizing organization so that real or apparent conflicts of interest are avoided.

Audit scheduling depends on the size of the project, the project duration, and the specified quality of the data (see DQOs) . Projects in category I and II will be audited at least every two years and other projects every three years . An EPA Project Leader may request an audit based on information presented in project progress reports, or results of prior audits, performance evaluations or other situations where there is concern for the quality of data .

Audit reports are submitted by the QAM to the EPA Project Leader, through a Branch Chief and Program Leader . Written audit reports will contain a summary of the areas evaluated during the audit, statement on novel or good QA practices followed, and identification of problem areas.

When significant concerns are identified in the audit report, the Project Leader must develop an action plan to correct any significant deficiencies including a time frame in which to accomplish these actions . A copy of the plan shall be forwarded to the QAM, who will monitor corrective actions.

A **Performance Evaluation (PE)** assesses and documents how well the analytical system performs by using reference samples of known composition and concentration . This technique may be used as part of a pre-award evaluation or during a project . This technique is particularly useful for analytical or sample preparation procedures and should be included whenever practical . Performance evaluations are useful to evaluate the accuracy of measurement techniques, intra- and inter-laboratory precision and bias, and trend or performance over time . The frequency of PEs is dependent on the design of the project and the QA program . The resultant data should be compared with control limits established in the project DQO statement to identify compliance or out-of-control conditions . Performance evaluations (PEs) are the responsibility of the EPA Project Leader . Results of each PE will be summarized and will include a list of conclusions and recommended corrective actions . This report will be kept by the Project Leader and a copy sent to the QAM.

Management Systems Review (**MSR**)

Implementation of the WED Quality Management Plan is evaluated every three years by the NHEERL DQA . A review is conducted and a written report prepared and submitted to the Associate Director for Science of WED . Corrective actions and recommendations are identified.

List of web addresses appearing in the QMP:

EPA ORDER 5360.1 A2 May 5, 2000 POLICY AND PROGRAM REQUIREMENTS FOR THE MANDATORY AGENCY-WIDE QUALITY SYSTEM http://www.epa.gov/quality1/qs-docs/5360-1.pdf

ANSI/ASQC E4-1994 . . . . . http://qualitypress.asq.org/perl/catalog.cgi?item=T55

EPA Quality Manual for Environmental Programs http://www.epa.gov/quality1/qs-docs/5360.pdf

EPA Guidance for the Data Quality Objectives Process E PA (QA/G4) http://www.epa.gov/quality1/qs-docs/g4-final.pdf

EPA Requirements for QA Project Plans (QA/R-5) http://www.epa.gov/quality1/qs-docs/r5-final.pdf

EPA Guidance on Quality Assurance Project Plans (QA/G-5) http://www.epa.gov/quality1/qs-docs/g5-final.pdf

NHEERL Quality Management Plan (QMP) . . . . . http://www.herl.epa.gov/nheerl/ood/adh/ntdqaqm.pdf

ORD Clearance form (EPA 362 Rev 2/97) . . . . . FORM ORD-362.wpd

Publication Review and Clearance Procedures (WED Policy #2260.1). . . . . http://www.epa.gov/wed/pages/QA/clearanceprocedures.htm

FUNDING CLEARANCE Quality Assurance Review form . . . . . FORM(WED-26)-Fundingclearance.wpd

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APPENDICES & FORMS

APPENDIX Number of Pages

FORMS

QA POLICY

EPA Quality System Documents Requirements for EPA Organizations:
(http://es.epa.gov/ncerqa/qa/qa_docs.html) This web address provides a list and current status of EPA requirement and guidance documents. It also provides links to the current versions.

EPA Order 5360.1 A2 (May 5, 2000)
(http://www.epa.gov/quality1/qs-docs/5360-1.pdf)
Policy and Program Requirements for the Mandatory Agency-Wide Quality System. This is the primary instruction upon which all EPA QA programs are based.

EPA Manual 5360 A1 (May 2000)
(http://www.epa.gov/quality1/qs-docs/5360.pdf)
EPA Quality Manual for Environmental Programs defines program requirements for EPA organizations in implementing the mandatory Quality System defined in 5360.1 A2.. Equivalent specifications are defined in Requirements Documents for organizations receiving financial assistance from EPA through extramural agreements.

Requirements for non-EPA Organizations: (follow this link to all requirement documents listed below)
(http://www.epa.gov/quality1/qa_docs.html)
Quality requirements for non-EPA organizations are defined in the Code of Federal Regulations and the Quality Staff in the Office of Environmental Information (OEI) has issued documents to provide information on satisfying the Federal Regulations. These documents contain policy statements that identify and discuss mandatory elements of the Agency's Quality System for organizations receiving financial assistance from EPA through extramural agreements (e.g., contracts, grants, cooperative agreements, and interagency agreements). These documents may be used by EPA organizations as well.

EPA Requirements for Quality Management Plans (QA/R-2)

EPA Requirements for QA Project Plans (QA/R-5)

Guidance for Implementing Requirements: (follow this link to all guidance documents listed below)

(http://www.epa.gov/quality1/qa_docs.html)The Quality Staff also issues documents to assist in the development and implementation of a suitable Quality System for both EPA and non-EPA organizations.

Guidance for the Data Quality Objectives Process (G-4)

Decision Error Feasibility Trials (DEFT) Software (G-4D)

Guidance for the Data Quality Objectives Process for Hazardous Waste Sites (G-4HW)
Guidance on Quality Assurance Project Plans (G-5)

Guidance on Sampling Designs to Support QA Project Plans (G-5S)

Guidance for the Preparation of Standard Operating Procedures (G-6)

Guidance on Technical Audits and Related Assessments (G-7)

Guidance for Data Quality Assessment: Practical Methods for Data Analysis (G-9)

Data Quality Assessment Statistical Toolbox - DataQUEST (G-9D)

Guidance for Developing a Quality Assurance Training Program (G-10)

MODELING

Quality assurance guidelines for modeling development and application projects: a Policy Statement*. November 1991. Environmental Protection Agency Environmental Research Laboratory Duluth. *This outline is official policy at MED and may be used at WED at the discretion of the project Leader. Copies are available in the QA office or by pressing the linking icon below.*

GLOSSARY

The definitions listed below represent standard language to the extent it is applicable. Exceptions are for the terms accuracy, completeness and precision. Definitions found in other sources are generally identical, but suggest that a mathematical presentation for the reverse concept. In example consider the definition for precision which is typically unambiguous and described by words similar to those presented below. However, as a final sentence in the definition there is often a statement requiring that the values of precision reflect standard deviation expressed as the coefficient of variation (CV). Clearly the CV describes the imprecision, not precision. We prefer to express the words and values with similar connotations. The terms of accuracy and completeness follow similar arguments.

Accuracy - An indication of how close measured values are to the true value. One manner of expressing this is as 100% minus the % deviation (absolute value) from the true value.

Accuracy (%) = $(1.0 - |(\sum(V_t - V_m)/n)/V_t| * 100$
where:
V_t is the true or standard value
V_m is the measured value

Other mathematical expressions are also valid and are acceptable. Use of the above absolute (based on %) scale hides the aspect of bias which may be important information. Removal of the absolute signs will yield + or - values which reveals bias as well as accuracy. If this practice is used interpretation of values greater than 100% must be understood to be less than accurate since, by definition, no value can be more than perfectly accurate (i.e. 100%).

Bias - the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Calibration- To make adjustment (as in adjusting an instrument to present the correct response to some measurement). A calibration curve is often created by measuring different known concentrations and plotting the known values against the machine response. By applying the slope of such a curve to machine outputs, the measurements are adjusted to yield calibrated values. Note the difference between calibrating (making an adjustment) and making a measurement and comparing the value with the know quantity of the standard.

Comparability - The degree of confidence with which two or more sets of data may be compared. Data comparability is dependent upon consistency in sampling conditions, selection of sampling procedures, sample preservation methods, analytical methods, and data reporting units, throughout the project, and with the previous projects with which these results will be compared. All these factors are qualitative and hard to measure. Comparability of data is generally best described in a narrative statement which references the items listed above.

Completeness - During experimentation or monitoring, some samples may be impossible to secure, some measurements may become lost, or be inaccurate because of malfunctioning equipment, among other reasons. Completeness is the % of values available for evaluation. The number of missing values influences the usefulness of the statistical evaluation of the information and too many missing values will, at some point, become unacceptable for the desired goals.

Completeness (%) = $(1.0 - (N_e - N_o)/ N_e) * 100$
where

N_e is the number of measurements expected.
N_o is the number of measurements obtained.

Performance Evaluation (PE) is accomplished by different procedures: One procedure involves assessing and documenting how well the analytical system performs by using reference samples of known composition and concentration. Another procedure involves comparing analytical results of true replicates (generally standards) by independent analyst or laboratories.

Precision- An indication of the similarity of repeated analyses or sampling. A useful method of expression is as 100% minus the coefficient of variation of repeated measurements.
Precision (%) = $(1.0 - SD/\bar{x}) * 100$
where:
SD is the standard deviation
$\bar{x}$ is the mean

Alternately the standard deviation or coefficient of variation may also be used. The exact nature of the precision index should be specified to eliminate possible confusion. I.e. When the coefficient of correlation is used smaller values are associated with greater precision and the index is therefore intuitively reversed.

Quality Assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Assurance Audit (QAA, QA Audit, or simply Audit) consists of a thorough on-site evaluation of a research activity. Audits are used to evaluate the existence and adequacy of all equipment, facilities, supplies, personnel, and procedures that are either used directly for, or in support of, the collection and interpretation of data. In addition, audits are used to evaluate the documentation associated with data quality indicators.

Quality Control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the client.

Representativeness - a measure of the degree to which the data accurately and precisely represent a characteristic of a population parameter, variation of a property, a process characteristic, or an operational condition.

For more information see:
EPA Quality Manual for Environmental Programs. May 1994. Appendix A, Terms and Definitions. The definitions in that document are taken from an extensive list including the ISO 8402-1994, *Quality Management and Quality Assurance - Vocabulary*. When differences were evident a consensus definition was based on reviewers' comments and on the application of the term to environmental use.

APPENDIX 3: QUALITY ASSURANCE PROJECT PLANS (QAPP)

INSTRUCTIONS FOR PREPARING A (QAPP)

Agency policy regarding QAPP development will be followed at WED as contained in: EPA Requirements for QA Project Plans (QA/R-5) and guidance for writing is in: Guidance on Quality Assurance Project Plans (G-5). An abbreviated guidance with suggested outline is contained below:

Graded approach: WED recognizes that a "one size fits all" approach to quality requirements for research will not work. The level of detail in the QAPP will vary according to the nature of the work being performed and the intended use of the data.

Each project will be assigned a category according to the criteria listed on page 3 of the WED QMP.

Exemptions: It is recognized that under some circumstances it is necessary to conduct preliminary experiments or range finding tests to facilitate appropriate experimental design which will form the basis of a QAPP. It is also obvious that for some low cost purchase orders or COOPs, the cost of developing a QAPP is disproportionate to the task. Other projects which consist entirely of developing a policy or reviewing an area of science may make writing a QAPP useless. Request for exemption should be submitted in a memo from the project leader, thru the branch chief, to the QAM. It should contain:

- explanation of the intended work
- reasons for wanting an exemption
- requested period
- appropriate signatures.

Inclusions: Any document which is supplemental to the QAPP and which defines or prescribes procedures that contribute to the quality of data, is considered an integral part of the QAPP and therefore requires the same management and QA approval as for the QAPP. This typically includes SOPs, and amendments and alterations to the QAPP.

Format: The same format should be used for all (in-house, extramural, experimental, analytical, modeling, data manipulation, etc.) projects sponsored by WED. It is obvious that not all sections apply equally to all types of projects. Thus, when a section is irrelevant, a simple note indicating that it is not applicable, with an explanation where necessary, should be included.

The recommended format presented in this appendix allows different approaches to the development of QAPPs. For a simple project, the QAPP may contain the entire set of instructions needed to complete a project. For a complicated, extensive project, the QAPP may be composed of a summary of goals, management, organization, and any other portion that lends itself to a general treatment, with associated SOPs which detail the procedures for various tasks. The advantage of the latter approach is that the QAPP is conveniently divided into manageable portions, which can be added or amended as different tasks are approached. SOPs should include many of the elements of QAPPs and at WED the same format is suggested. EPA provides an alternate format which may be useful: Guidance for the Preparation of Standard Operating Procedures (SOPs) for Qualtiy Related Documents, EPA QA/G-6
The development or application of **mathematical models** and the use of **pre-existing data** garnered from the literature, databases, or archived files, presents unusual problems in describing the procedures for quality assurance. We suggest that the format described below, with appropriate modification, may also serve those projects. Obviously all headings don't apply (i.e. sections for instruments, calibration, quality control, preventive maintenance etc. will typically have no relevance). Some suggestions are included under the heading: Modeling/database projects. The quality assurance plan, regarding these projects, should focus on the procedures used to capture and utilize (or acknowledge the lack of)

information regarding data quality and the probable impact of imprecision in the assumptions or rules used to build and apply models of environmental conditions.

Examples: At the end of this appendix are several examples. These should **not** be considered as a mandatory format, but rather examples of organizational tools that may be applicable to some of the needs of your project. Follow the examples when they are useful, but feel no obligation to force material into that format when it does not facilitate the presentation of information.

The following elements should be included in a QAPP. Explanations and suggestions are available in the Guidance on Quality Assurance Project Plans (G-5).

PROJECT MANAGEMENT

INTRODUCTION

Present a brief introduction describing the need for the research, how this work relates to previous work, and the context of the project in relation to accepted knowledge and practice (literature review). An extensive introduction presumably already exists in the proposal or Research Plan which was intended to convince the reader of the need and worthiness of this project. Please don't copy that introduction, but rather make this brief, but sufficient for the reader to understand why the work is important.

Goals List the goals of the project. This section is also not intended to be a treatise of the research, nor a justification for work, but a simple statement of goals so that the reader can understand how the methods match the intended results. Project deliverables and a schedule for their completion should be agreed upon between the principal investigator and the Project Leader and stated in this section.

Organization Explain the QA organization of the project. Identify all project participants (especially the PI(s)) and their roles and responsibilities for all planned tasks. Identify lines of project responsibility for each task or group of measures. Subcontractors should be included in the description. A flow chart may be a useful way of presenting the lines of responsibility.

DATA QUALITY OBJECTIVES (DQOs)

DQOs establish the data user's requirements for precision, accuracy, completeness, representativeness, and comparability. There are two forms for developing DQOs: the first is primarily for research and the second is a more formal process for monitoring or research done specifically to support an EPA regulatory decision. WED research falls mainly within the first type and this outline presents only the short form for research. The formal DQO process is presented in the EPA guidance document (Guidance for the Data Quality Objectives Process (G-4) and includes a description of when it should be used. This document along with a tutorial Decision Error Feasibility Trials (DEFT) Software (G-4D) can be obtained on line.

One method to determine the required data quality objectives (DQOs) is to make a list of all measurements needed to answer the questions posed in the research. Determine the level of precision, accuracy, and completeness needed to accomplish your goals. This can often be presented in a table format (example table 1). It is important to remember that the values presented as your data quality objectives will be the standards for evaluating the data collected. Make sure that the DQOs reflect the needs of the project and are not too restrictive or too lax. Remember that the DQOs may be changed if in the course of the project you have been too optimistic regarding your measurement ability or that your analysis requires greater precision, accuracy or completeness.

Modeling/database projects. DQOs are typically not applicable to modeling activities. Where existing data are used (i.e. in modeling, GIS exercises and in reviews) the quality of data to be used should be specified in the DQO in the same manner as if measurements were part of the research plan. Data quality will, obviously, dictate the research design and should be addressed in that discussion. If no QA indices exist, a plan to acknowledge that condition and to appropriately alert the reader of the output should be included.

MEASUREMENT / DATA ACQUISITION

STATISTICAL RESEARCH DESIGN

The selection of an appropriate research design for specific objectives is a crucial step in optimizing available resources and in determining the success and applicability of a study, whether data are developed or existing data are used. The number and kind of factors controlled or observed, the pattern of randomization, and the extent of sample and analytical replication in a study determine what hypotheses are testable, whether relationships can be fit, the precision of estimates, and the range of conditions over which inferences may be made. A statistical research design focuses on specific objectives, but in so doing, may limit the application of the results. No research design has universal application.

Projects designated as "range finding" shall follow the same tenets. However, range finding projects may require deviations which must be documented in writing and caveated appropriately during the planning phase.

SAMPLING

For each sample type, describe sampling methods and analytical procedures. Many procedures lend themselves to description as standard operating procedure (SOP) a practice recommended when it will clarify and compartmentalize description of specific tasks. When an SOP is used, reference in this section should direct the reader to its location. Help in sampling design will be available in the near future as an EPA document: Guidance on Sampling Designs to Support QA Project Plans (G-5S).

Modeling/database projects. Delete this section if it does not apply.

Methods
Describe procedures for selecting, collecting and handling samples. Many of these items can be most effectively presented in tables (example table 2) or lists, other items need a more detailed presentation. Make certain that sufficient information is presented to clarify the procedure and allow judgement of appropriateness and completeness. Some of the items which should be

considered are listed below:

- What rules are used to select sampling points and frequencies?
- What procedures are to be used in collecting samples? This may include decontamination of sampling implements, identification of temporal and spacial conditions of the sample, corollary information (weather conditions, slope, etc.)which identify the sample in a manner meaningful to the goal of the experiment.
- Preparation of sample containers
- Specification of sample volumes
- Preservation methods, maximum holding times.
- Record keeping procedures. Attach field sampling data sheets, sample inventory forms, shipping forms, and any other forms used in this process.
- Sample labeling
- Sample handling, transportation and custody. This instruction is particularly important for monitoring studies that may become the basis for litigation or if samples will be analyzed by different subcontractors or shipped. Discuss an approach for verifying sample receipt and evaluation of sample condition upon receipt, security within sample storage areas, and sample archiving (location, labeling). Identify how long samples are required to be stored after analysis and if samples should be stored after holding times are exceeded.

Analysis

Describe the analytical procedures used for each sample. If standard methods (i.e. methods described by American Society of Testing Materials (ASTM) or American Public Health Association (APHA), etc.) are used, provide a copy of the procedure as an appendix. Analysis often depends on an instrument which measures some parameter of the sample. A useful presentation can often be organized by instrument although in some systems other approaches may be easier to understand. When measurements don't depend on an instrument (i.e. bird census determined by identifying bird songs along a prescribed transect) use this heading to describe the process of measurement. Some of the items which should be considered are listed below:

Instrument: Make a list of the instruments, the parameters measured, and the inferences to be made. This list will clarify the measurement procedure and be useful for the person making the measurements and the person reviewing the plan. This may be presented in a table (example table 3), a list or in paragraph format.

Calibration: The intent of this section is to identify the needs and procedures for calibration. Describe how and when the instrument will be calibrated (example table 4). Describe the traceability of the calibration standard to some authenticated system and describe the procedure for maintaining standards. It is important to distinguish the difference between calibrating and checking accuracy. To calibrate an instrument is to adjust the output so that the reading is accurate. For a balance, this may be accomplished by adjusting the tension on a spring or adjusting a potentiometer. For a spectrophotometer this may be accomplished by making a standard curve of a dilution series and applying the mathematical fit (calibration curve) to the measurements of unknown samples. Some instruments need calibration frequently (i.e. a pH meter is calibrated each time it is used), while others need calibration rarely (i.e. a balance). Some instruments require calibration at several concentrations. Often instrument detection limits determine the accuracy of measurements at the extremes of instrument sensitivity. Although values may be recorded by some instruments, those values may have no meaning if they fall outside detection limits. For those measurement systems

with either high or low limitations a description of how to deal with values that fall outside acceptable limits must be described *a priori*..

Quality Control (QC): Describe the procedures used to evaluate the instrument and the quality (precision and accuracy) of data being collected. In most analytical systems, accuracy is determined by routine and periodic measurement of standards and blanks. Describe the procedures for introduction and evaluation of standards and blanks. These procedures will differ between instruments and will vary from the simple measurement of standard weights before and after each measurement session to the insertion of blanks, blind replicates of samples, and standard chemical preparations into a GC sample train. Describe how this process will be accomplished and how the data will be compared to DQOs and what rules will govern the acceptance, modification or rejection of data. This presentation can often be facilitated by displaying some information in tables (example table 5). These procedures should be completed as quality control (QC) samples are analyzed. QA/QC data should be stored in a format associated with the coincident data. An easy way to accomplish this is to create an additional column (in a spread sheet) or file (in a relational database) which will naturally accompany the data collected from the session covered by the standard measurements. Analytical precision is a considerably different thing than sampling precision. Both should be known to evaluate an environmental condition.

Consumables: Where consumable items, such as solvents, standard gasses, reagents, etc. are involved, discuss acceptability rules and procedures used to inspect and evaluate.

DATA MANAGEMENT Trace data from collection to the final report. This may include various steps such as: entry into field notebook, transcription into computer spread sheet or database, verification, proof reading, outlier identification, editing, analysis, report writing. Include identification of units, when they change and how such changes are accomplished, (i.e., original data may be captured as peak height from some detector, changed to quantity based on a standard, changed to concentration by dividing by amount injected into detector, changed into concentration of tissue by dividing by mass of tissue in the sample, changed to concentration on area basis by a regression of mass to area, and finally reported on the basis of amount per hectare by another regression). The issue for QA is to specifically identify each data transformation and justify the use of auxiliary information when it is used to alter the values or the form of presentation. Some modifications introduce additional error, such as the error in measuring a second variable like area or mass. It is important to propagate all errors associated with any data generated in the laboratory or obtained from the literature.

Provide information on your computer system, method and frequency of file back-up. Discuss how long sample data should be stored, by whom and where.

Modeling/database projects. Many modeling studies are done without data or use values obtained from the literature. In these studies it is important that attention be given to identify, to the extent possible, the QA indices of data quality. It is important to associate the outputs of the research with the errors inherent in the building pieces.

Include a description of the procedures used to keep track of model versions. A “meta data” system is a useful procedure and serves the same purpose as a laboratory notebook for documenting sources of information, and changes made including the reasons for change.

ASSESSMENT / OVERSIGHT

Identify the frequency, and type of assessment activities for this project. Assessments include, but are not limited to the following:

- surveillance
- peer review
- performance evaluation
- audits

Describe the procedures that best serve this project and provide an outline to implement the assessment activity. Explain how the project will be internally reviewed and state how the results of your review will be acted upon and documented.

AUDITS - The QA staff at the WED have the responsibility to perform audits of all projects. The goals are to: (1) evaluate the implementation of the QAPP, and (2) provide assistance regarding QA procedures. Audits are often useful prior to or at the commencement of sampling or analysis. Regular audits should be performed every two years or earlier at the request of the Project Leader. Include a proposed audit schedule with consideration of sampling and analytical periods and times when an audit would be disruptive (i.e. test week or vacation times). The proposed schedule is intended only as a guide and audit times will be arranged by the mutual consent of the Project Leader and the QA staff.

Modeling/database projects. Audits by the QA staff may have no practical value. Provide a plan for monitoring the procedures outlined in the QAPP.

QA REPORTS - This section should specify the frequency of progress reports to EPA and define an approach to address project QA/QC in the final deliverables. The QA portion of the progress reports should address:

- A summary of precision, accuracy and completeness for all samples analyzed.
- Any problems that could affect the quality of the data collected, the project schedule or the completion of the project;
- A summary of any corrective actions implemented and the result;
- Changes in the project's experimental design, objectives, or staffing;
- The need for additional equipment to achieve project objectives.
- Identify any problems with equipment.
- A summary of data quality evaluation (especially for modeling or data review projects).

DATA VALIDATION AND USABILITY

- State the criteria used to review and validate data.
- Provide examples of any forms or checklists to be used.
- Identify any project-specific calculations required.

UPDATES AND REVISIONS

Many good and useful ideas regarding research are not conceived prior to experimentation and are therefore not included in QAPPs or SOPs. Also, because research is complex, changes to original QAPPs are sometimes needed. The Project Leader is responsible to determine if an anticipated change will impact the quality of the project. If a change is desirable, the change should be submitted

for approval through the same channel as the original.

QAPP

FOR

PROJECT TITLE

Assistance agreement number (extramural projects)
Project Leader:
Principal Investigator:
Institution:

EXAMPLE

TITLE PAGE

Project TITLE

Management Approvals:

Signature indicates that this QAPP is approved and will be implemented in conducting the research of this project.

Name (Branch name) Branch Chief	*Signature*	*Date*
Name (Program name) Program Leader	*Signature*	*Date*
Name Project Leader	*Signature*	*Date*

Extramural **Project Managers and/or Principal Investigators**:[1]

Signature indicates commitment to follow the procedures in this QAPP.

Name		
Principal Investigator	*Signature*	*Date*

Quality Assurance:

Signature indicates that this QAPP meets the quality requirements of WED.

Craig Mc Farlane Quality Assurance Manager	*Signature*	*Date*

EXAMPLE

APPROVAL PAGE

1 A chain of responsible persons should be established where signatures are required for each independent PI or manager. Subordinates do not need to sign the approval page.

Distribution List

List the individuals and their organizations who will receive copies of the approved QAPP and any subsequent revisions. Include all managers who are responsible for implementing the plan, as well as the QA managers and representatives of all groups involved.

CONTENTS

Content **Page**

The following tables are presented as examples of one way to organize and present some of the information in a QAPP. These tables should not be regarded as a prescribed format since the appropriate format necessarily varies with the type of research described.

Table 1. Data quality objectives

Parameter	Measurement units	Expected range (units[1])	Accuracy (%)	Precision (%)	Completeness (%)
Leaf mass (dry)	g	0.5 - 2.0	98	98	95
Benzene concentration	µg/ml	10 - 500	95	90	95
Soil Temperature	C	-20 to 40	95	95	100

1. Expressed in the same units as measured.

Table 2. Summary of sample collection, handling, and preservation activities

Sample Type[a]	Parameter(s) Measured	Sample Container	Minimum Sample Size	Preservation Method/Storage	Maximum Holding Time
Stream H_2O	pH	syringe	50 ml	Store on ice	4 hours
Soil	Pesticide concentration	plastic, 1-L HDPE[b] or glass	50 g	Store on ice	28 days
Leachate collected from lysimeter	N, TKN[c]	1-L HDPE[b]	500 ml	H_2SO_4 < 2 pH Store on ice	28 days
Leaves	dry mass (g)	paper bag	25 g	dry at 100C for 24 hrs.	6 months
Audio recording	bird songs	audio cassette	3	NA	1 year

a For example - air, soil, through-fall, lysimeter, stream, lake, tissue, blood, plant tissue
b High density polyethylene
c Total Kjeldahl Nitrogen

Table 3. Instrument Calibration

Instrument	Calibration procedure	Frequency
Mettler balance PM3000	Calibrated by factory service technician (if needed) during annual maintenance	yearly
Gas Chromatograph	Calibration curve determined by injecting concentration standards covering expected range injected.	each session
pH meter	Adjust meter using standard buffers.	each session
Lambda PAR sensor	Returned to manufacturer for spectrum verification and intensity calibration	yearly

Table 4. Quality control checks for instruments

Instruments	Q.C. Check	Frequency	Data summary	Acceptance criteria	Action if values are unacceptable
Mettler balance PM3000	Record readings for NIST traceable standard weights that cover the range of expected values	before and after each session	calculate accuracy	greater than DQO	Re-weigh all samples on another balance. Clean, adjust or send balance for repair.
Oxford and Eppendorf pipettes	determine mass of dispensed volume	before each session	Single measure-ment	Within ± 1% of expected volume	Clean, adjust, replace pipette. Send defective pipette to supplier for maintenance.
Gas Chromatograph	Concentration standards covering expected range injected.	before each session	Plot dose / response curve.	linear response, R^2 > .95	repeat standards injection until linear response. Clean detector, or otherwise repair instrument.
Trained observers (bird songs)	Test observers against experts using audio tapes or field trials.	yearly	Species count	accuracy > 80%	Retrain and re-test.

Table 5. Preventive maintenance

Instrument	Frequency	Preventive Maintenance
Mettler balance PM3000	yearly	Contract service
Gas Chromatograph	yearly or when column is changed	detector cleaned, diagnostic self test
Oxford and Eppendorf pipettes	yearly or when QC checks are unsatisfactory	replace gaskets, lubricate, clean, use contract maintenance service.

QUALITY ASSURANCE GUIDELINES FOR MODELING DEVELOPMENT AND APPLICATION PROJECTS
a Policy Statement

November 1991

Environmental Protection Agency
Environmental Research Laboratory
6201 Congdon Boulevard
Duluth, Minnesota 55804

APPROVED: _____ DATE:_____
Gilman D. Veith, Director

Developed by the Modeling Project Quality Assurance Subcommittee, members A. Pilli (Chair),R. Erickson, M. Hanratty, J.H. McCormick, J. Nichols, C. Russom, D. Endicott, and J. Westman. Reviewed by several agency OAMs and contractors with their comments incorporated where practical to ERL-D applications.

Table of Contents

Quality Assurance Guidelines for Modeling Development and Application Projects

I Introduction

The principal idea behind quality assurance guidelines is to insure that minimum standards of quality are achieved during the modeling process. The main mechanism for implementation is to maintain accountability of all activities and results. Quality assurance guidelines for modeling are crucial to both model development and model application; they should be an integral part of project planning and should be applied to all phases of the modeling process. A classification of mathematical models is provided in Section V.

Quality assurance procedures can provide safeguards against faulty models, improper modeling or inappropriate application. However, regulators and decision makers should understand that there is no way to guarantee that modeling-based advice is entirely correct or that the model can ever be proven, verified, or validated in the strictest sense of these terms. Rather, a model can only be invalidated by disagreement of fts predictions with independently derived observations regarding real systems (van der Heijde 1989).

A major role of the quality assurance process in modeling is to provide documentation of procedures so that the modelers, peers, and decision makers are aware of the accuracy, uncertainty, and reliability of the model. Quality assurance procedures should never become so cumbersome that modelers are reluctant to explore new avenues or that an inappropriately large part of the project budget is consumed by procedural requirements. Furthermore, the risk that quality assurance procedures may deteriorate to become only a checklist for installing false confidence in modeling results should also be avoided (van der Heijde 1989).

II Definitions

A. Quality assurance (QA) is the procedural and operational framework put in place by the organization managing the modeling study to assure technically and scientifically adequate execution of all project tasks included in the study and to assure that all modeling-based analysis is verifiable and defensible (Taylor 1985).

B. Quality control (QC) refers to the procedures that ensure the quality of the final product. These procedures include the use of appropriate methodology, adequate validation, and proper use of the selected methods and models (van der Heijde 1989).

The following definitions for procedures used in QC are based in part on Blacker 1989.

(a) **accuracy -** the closeness of agreement between an observed value and the accepted true value
(b) **bias -** a constant or systematic error
(c) **calibration -** the ability of the code to fit field data (Ward et al. 1984)
(d) **comparability -** the applicability of the data base(s) for answering scientific questions, e.g., do differences in objectives, designs, methods, or analyses among the data base(s) limit their usefulness collectively
(e) **completeness -** the limitations of the data base(s) due to missing data, e.g., were measurements for a crucial time period or whole treatment missing (U.S. EPA 1987)

(f) **precision -** the degree of mutual agreement among individual measurements of the sam@e property
(g) **prediction -** the ability of the model to fit experimental data using modeling--independent estimates of the parameters (typically unavailable)
(h) **reliability -** the probability that an item will perform a required function under stated conditions for a stated period of time
(i) **representativeness -** the degree to which data accurately and precisely represent a characteristic
(j) **uncertainty -** the sources of inherent variability of input data and model parameters
(k) **validation -** comparison of model results with numerical data independently derived from experiments or observations
(l) **verification -** confirmation that original intent of the user requirements is represented

C. Quality assessment is applied to monitor the quality control procedures and to evaluate the quality of the modeling study through auditing and technical review. Audits determine the degree of compliance with QA requirements while technical reviews evaluate the technical and scientific basis of the project (van der Heijde 1987).

III Quality Assurance Plan Guidelines (U.S. EPA 1987)

A Quality Assurance Plan should be submitted as part of the work plan at the beginning of a model development or application project. The **OA** plan should contain a complete set of OA procedures. These procedures should list the degree of quality and the measures required to achieve prescribed quality objectives. The OA plan should also detail the format for OA reports which will summarize the data quality and associated OA/QC activities. OA/QC data may be requested periodically and must be accessible to the QA staff during project reviews.

A recommended format for the OA plan is provided in Section 111. The following Sections A-E provide detailed guidance for the recommended sections of a Quality Assurance Plan.

A Project description (Responsibility of the Project Manager)

The project description should include the following:

1. a brief statement of the scope, purpose, and objectives of the project;

2. the product(s) and a timetable for completion;

3. a diagram showing the project personnel, their titles and duties/responsibilities, and the lines of authority and information flow among them;

4. a short narrative about individual responsibilities when they cannot be clearly delineated in a diagram;

5. a brief discussion about the key support facilities and services used (including computer facilities);

B Model description (Responsibility of the model developer)

The model description should include:

1. Model parameters (U.S. EPA 1987)

   (a) model origin and fts original purpose
   (b) parameters and variables
   (c) spatial extent (individual, group, population)
   (d) spatial resolution (location independent/dependent, dimensionality)
   (e) temporal extent (length of modeling period)
   (f) temporal resolution (time step)
   (g) model structure (e.g., theoretical vs. data driven, stochastic vsdeterministic, structural framework)

2. Computer aspects (U.S. EPA 1987)

   (a) programming language (FORTRAN, BASIC, etc.) and ANSII standard
   (b) model portability
   (c) memory requirements
   (d) required hardware/software for application (monitor, line printer, graphics
   (e) approximate execution time for a typical run

3. Data quality (U.S. EPA 1987)

The purpose of assessing data quality is to evaluate, to the extent possible, the reliability of the existing data base(s). Procedures for determining precision, accuracy, representativeness, completeness, and comparability of existing data should be summarized. Specific parameters to be discussed include:

(a) source of original data and criteria for acceptance or rejection
(b) any modifications from original data
(c) sampling protocol
(d) data format, maintenance, and archiving

C Model development

1. Code development and maintenance (van der Heijde 1989)

   OA for code development and maintenance should include complete record keeping of the model development, of modifications made in the code, and of the code validation process. The media trail for QA in model development consists of reports and computer files on the development of the model. The reports should include a description of:

   - assumptions
   - parameter values and sources
     changes and verification of changes made in code actual input used
   - output of model runs and interpretation
   - validation (or at least calibration) of model

   In addition, the following files may be retained (in hard-copy and, at higher levels, in digital form):

   - version of source code used

- verification input and output
- validation input and output
- application input and output

If any modifications are made to the model coding for a specific problem, the code should be tested again; all OA procedures for model development should again be applied, including accurate record keeping and reporting. All new input and output files should be saved for inspection and possible reuse.

2. Model documentation

Computer model documentation is defined as the information recorded during the design, development, and maintenance of computer applications, in order to explain pertinent aspects of a data processing system, including purposes, methods, logic, relationships, capabilities, and limitations (Gass 1979). It is the principal instrument of communication used by the model author, the model user, and the system operator.

Good documentation includes a complete description of:

- the equations on which the model is based
- the underlying assumptions
- the boundary conditions that can be incorporated in the model
- the method used to solve the equations
- limiting conditions

The documentation must also include:

- user's instructions for operating the code
- instructions for preparing data files
- example problems complete with input and output
- programmer's instructions
- computer operator's instructions
- a report of the initial code verification

3. Code verification

The objective of the code verification process is to check the correctness and accuracy of the computational algorithms used to solve the governing equations and to assure that the computer code is fully operational. It should be noted that most models are verified only with respect to segments of their coding or for only a part of the tasks for which they were designed.

4. Code documentation

The inspection of the computer code is part of the model review process. In this inspection, attention is given to the manner in which modern programming principles have been applied with respect to code structure, compliance with programming standards, efficient use of programming languages, and internal documentation. This step may reveal programming or logic errors that are difficult or impossible to detect in verification runs.

The code documentation should include:

- model specifications
- model description
- flow charts
- description of routines
- data base description
- source listing
- error messages.

D Model Validation (Responsibility of model developer)

Model validation is defined as the comparison of model results with numerical data independently derived from laboratory experiments or observations of the environment. For many types of models, a complete set of test problems and adequate data sets for the described testing procedure is not yet available. Development of such data sets is critical in establishing the validity of models.

Model development is an evolutionary process responding to new research results, developments in technology, and changes in user requirements. Model validation needs to follow this dynamic process and should be applied each time the model is modified.

E. Model application (Responsibility of the Project Manager)

Model application quality assurance procedures should provide a clear formulation of the project objectives and the modeling approach used to meet these objectives. The specific rules for proper application of the model should be documented and available to users. The softability, reliability, and efficiency of the model should be addressed (van der Heijde 1981).

Restrictions of model application (van der Heijde 1989) should be outlined. Additionally, those which are accounted for by the code and those which are the responsibility of the user should be identified. Categories of restrictions include:

- assumptions
- parameter values and sources
- boundary and initial conditions
- validation/calibration of the model
- output and interpretation of model runs

Whether a model is valid for a particular application should be assessed by using performance criteria (van der Heijde 1989). Using these criteria, three levels of validity for single variable models can be distinguished as outlined below:

- Statistical Validity: Using statistical measures to check agreement between two different distributions, the calculated one and the measured one; validity is established by using an appropriate performance or validity criterion (ASTM 1984).

- Deviative Validity: if not enough data are available for statistical validation, a deviation coefficient D can be established. The deviation coefficient might be expressed as a summation of relative deviations.

- Qualitative Validity: Using a qualitative scale for validity levels representing subjective judgement e.g., excellent, good, fair, poor, unacceptable. Qualitative validity is often established through visual inspection of graphic representations of calculated and measured data.

The aforementioned tests apply to single variables and determine local-or single variable validity; if more than one variable is present in the model, the model should also be checked for global validity and for validity consistency.

There are analogous tests for multivariate systems:

- Qualitative validity: Can be determined one variable at a time using a series of graphic representations.

- Deviative validity: Can be measured using a vector, or state space, approach (Johnson and Bartell 1988), where the deviation coefficient is the distance between two vectors in a multidimensional space.

- Statistical validity: Can be measured using a state space approach and an appropriate muftivariate statistical measure such as muftivariate analysis of variance (Morrison 1990, Gauch 1982, Johnson & Wichern 1982).

IV Example Quality Assurance Plan Outline

A. Project Description

1. scope, purpose, objectives
2. products, completion timetable
3. project personnel
4. key support facilities and services

B. Model Description

1. model parameters
2. computer aspects
3. data source/quality/input-output

C. Model Development

1. code selection, development and maintenance
2. model documentation
3. code verification
4. code documentation

D. Model Validation

E. Model Application

1. outline restrictions
2. assess validity

V Classification of Mathematical Models (Blacker 1990):

- Static models, as those invariant in space and/or time;
- Dynamic models, as those varying in space and/or time;
- Deterministic models, as those with elements which are sufficiently specified, so that the model behavior, performance, or operation is exactly determined;
- Stochastic models, as those that use uncertainties or ... (random)...data, for which model behavior, performance, or operation is only probabilistically determined;
- Feedback models, as those in which the input depends on the output; such as in systems under control (either automatic or due to human intervention);
- Feedforward models, as those in which the output depends on the input, only, and no feedback exists;
- Analytical models, as those which describe the output via specific mathematical equations;
- Numeric models, as those through which the output is expressed, approximately, by numerical equivalents (used when one cannot feasibly solve the analytical expressions for the output);
- Mechanistic models, as those in which the model is based on any applications of physical or mechanistic theories governing the system; and
- Empirical models, as those used when the system's mechanisms are unknown, and the model is determined by statistically fitting equations to the data.

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* These references are not in our files. They have been cited in our existing references and are on order from the library.

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